

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
v.)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

8397

Bartle, C.J.

February 9, 2010

Carol Sage ("Ms. Sage" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In January 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Michael Liston, M.D.³ Based on an echocardiogram dated November 3, 2001, Dr. Liston attested in Part II of Ms. Sage's Green Form that she suffered from moderate mitral regurgitation and an abnormal left atrial dimension. Based on such findings, claimant would be

2. (...continued)
describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. As we previously have found, Dr. Liston is no stranger to this litigation. See Pretrial Order ("PTO") No. 6339 at 3 (May 26, 2006) (finding that Dr. Liston signed in excess of 1,600 Green Forms in total on behalf of claimants seeking Matrix Benefits).

entitled to Matrix A-1, Level II benefits in the amount of \$449,381.⁴

In the report of claimant's echocardiogram, Dr. Liston stated that claimant had "moderate mitral insufficiency with a regurgitant jet measuring 30% of total left atrial dimension." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In November 2002, the Trust notified Ms. Sage that her claim had been selected for audit.⁵ Claimant subsequently advised the Trust that she did not intend to submit additional

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

5. Under the Settlement Agreement, Wyeth and the Trust each designated for audit a certain number of claims for Matrix Benefits and identified the condition(s) to be reviewed during the audit. See Settlement Agreement §§ VI.E. and VI.F.; PTO No. 2457 (May 31, 2002), Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures") § III.B. Here, Wyeth identified for audit only claimant's level of mitral regurgitation. In PTO No. 2662 (Nov. 26, 2002), we ordered the Trust to audit every claim submitted for Matrix Benefits. The present claim was designated for audit prior to the court's issuance of PTO No. 2662.

medical information in support of her claim. The Trust then forwarded the claim for review by Waleed N. Irani, M.D., one of its auditing cardiologists. In audit, Dr. Irani concluded that there was no reasonable medical basis for Dr. Liston's finding that claimant had moderate mitral regurgitation. In support of this conclusion, Dr. Irani explained that there was "[m]ild mitral regurgitation with overestimated RJA + underestimated LAA determined through foreshortening."

Based on the auditing cardiologist's diagnosis of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Sage's claim. Pursuant to the Audit Policies and Procedures, claimant contested this adverse determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2457, Audit Policies and Procedures § IV.C.⁶ The Trust then applied to the court for issuance of an Order to show cause why Ms. Sage's claim should be paid. On April 8, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2826 (Apr. 8, 2003).

6. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Policies and Procedures contained in PTO No. 2457 apply to Ms. Sage's claim.

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 19, 2003. Claimant submitted a sur-reply on July 7, 2003. Under the Audit Policies and Procedures, it is within the Special Master's discretion to appoint a Technical Advisor⁷ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Policies and Procedures § VI.J. The Special Master assigned a Technical Advisor, James F. Burke, M.D., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. § VI.O.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. § VI.D. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue,

7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. § VI.Q. If, on the other hand, we determine that there is a reasonable medical basis, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id.

In support of her claim, Ms. Sage submitted several still frames from her echocardiogram, which purportedly demonstrate moderate mitral regurgitation. Ms. Sage also submitted an expert opinion from Frank E. Silvestry, M.D.,⁸ who opined that:

I measured the maximum regurgitant jet and measured its area using EchoAnalysis software. The jet I traced is an aliased Doppler jet emanating from the mitral valve in systole. The degree of mitral regurgitation is 20.5% with the maximal jet drawn shown

As per Green Form appendix endnotes #3 and #5, the maximal regurgitant jet is expressed as a percentage of the left atrial area. The auditing cardiologist may be expressing his or her qualitative opinion of the degree of mitral regurgitation; however, the Settlement documents specify a scientific and quantitative degree of mitral regurgitation, a degree that is clearly substantiated by the echocardiogram, and my independent measurements.

8. In his opinion, Dr. Silvestry provided the following disclaimer: "[t]he opinions rendered in this report are based on a reasonable degree of medical certainty, and are intended to provide legal consultation for forensic expert evaluation only. This report is not intended to provide medical opinions regarding treatment of the identified patient. No one should rely on the opinions expressed in this report for the diagnosis, prognosis or treatment of their medical condition. The interpretation above does not constitute a doctor patient relationship with the above client."

In addition, claimant argues that: (1) the requisite level of regurgitation need only be based on a maximum regurgitant jet; (2) the auditing cardiologist's conclusions should be given no weight because he did not explain his findings, and thus, "the Trust has not met its burden to deny payment of this claim"; and (3) under the Settlement Agreement, the auditing cardiologist was required to provide a specific measurement as to the level of regurgitation.⁹

In response, the Trust argues that there is no reasonable medical basis for Ms. Sage's claim because the auditing cardiologist determined that the attesting physician overtraced the regurgitant jet area and utilized a foreshortened view of the left atrium. The Trust further contends that claimant's experts improperly relied on a single regurgitant jet to support their finding of moderate mitral regurgitation. The Trust also argues that the auditing cardiologist complied with the Settlement Agreement in the manner in which he reviewed claimant's echocardiogram. Lastly, the Trust asserts that claimant cannot meet her burden simply by proffering additional opinions.¹⁰

9. Ms. Sage also asserts that the issue of reasonable medical basis should be controlled by the opinion of Gallagher v. Latrobe Brewing Co., 31 F.R.D. 36 (W.D. Pa. 1962). We repeatedly have rejected the Gallagher decision as controlling or persuasive. See, e.g., PTO No. 6275 at 9 (May 19, 2006).

10. The Trust also argues that under Federal Rule of Civil Procedure 26(a)(2), physicians who proffer opinions regarding (continued...)

In her sur-reply, claimant argues that the Trust erred in relying on Dr. Irani's report to deny her claim because Dr. Irani did not trace her mitral regurgitation or report the percentage of her mitral regurgitation. Claimant also suggests that the Trust misunderstands the concept of overtracing. According to claimant, "[t]he issue is not whether overtracing lacks a reasonable medical basis, but rather whether Dr. Liston did in fact overtrace in Ms. Sage's case." In addition, Ms. Sage asserts that her claim should be paid because both her attesting physician and her expert, Dr. Silvestry, reviewed her echocardiogram and concluded she had moderate mitral regurgitation. Finally, claimant submits that the Trust's statement that the judgments of Dr. Liston and Dr. Silvestry are colored by the fact that they receive an income for their reviews is both false and violative of Audit Rule 28.¹¹

The Technical Advisor, Dr. Burke, reviewed claimant's echocardiogram and observed that there was a large change in the level of regurgitation in the various views on the echocardiogram tape. Specifically, the level of mitral regurgitation appeared constant throughout several views, then changed to a much higher

10. (...continued)

claims must disclose their compensation for reviewing claims and provide a list of cases in which they have served as experts. We disagree. We previously stated that Rule 26(a)(2) disclosures are not required under the Audit Policies and Procedures. See PTO No. 6997 at 11-12, n.13 (Feb. 26, 2007).

11. Audit Rule 28 is the corollary to Section VI.H. of the Audit Policies and Procedures, which governs Ms. Sage's claim.

level in another view. The Special Master sent a letter to the parties requesting information concerning this sudden change in the level of regurgitation. In response, claimant submitted an e-mail from Dr. Silvestry, wherein he explained that:

As you know, regurgitant jets are directional, and therefore not fully imaged or visualized in all echocardiographic views, therefore the jet appears smaller in the parasternal long axis and apical 2 chamber views. In my review I sought to identify the most representative jet frames from the moving clips or images (and not necessarily the largest jet) for tracing and analysis, which in this case was in the apical 4/5 chamber views. The individual frames for tracing can be reviewed and reproduced by stepping through the study on a frame by frame basis.

Upon review, Dr. Burke concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation because claimant's echocardiogram demonstrated only mild regurgitation. Specifically, Dr. Burke found that:

My overall impression of the tape was that the patient has mild mitral regurgitation. I found very wide variability in the calculation of the regurgitant jet area to left atrial area. I am unable to explain this wide variability.

* * *

In the apical long axis view, I counted 8 beats with color flow Doppler imaging that were interpretable for MR assessment. All beats showed trace or mild MR. Averaging the beats with the most regurgitation, I calculated a RJA to LAA ratio of 8.4% - range for mild MR.

In the apical 4-chamber view, I counted 7 beats with color flow Doppler imaging that were interpretable for MR assessment. All beats showed trace or mild MR. Averaging the beats with the most regurgitation, I calculated a RJA to LAA ratio of 14.3% - range for mild MR.

The tape then shows three beats in real time of an apical view that appears somewhat in between a 2- and 4- chamber view. Although this does not represent standard views, this would not have affected the assessment of mitral regurgitation in my opinion. These are the beats used to measure the RJA/LAA ratio for the second reviewing physician's report - exhibit A-1 and A-2. I calculated a RJA/LAA ratio of 23.6% - in the moderate range - using these three beats.

* * *

In summary, this tape shows wide variability in the degree of mitral regurgitation from the beats near the end of the apical views and the findings on the remainder of the tape. I am at a loss to explain this wide variability. I reviewed the e-mail of Dr. Frank Silvestry regarding this issue, but even taking Dr. Silvestry's remarks into account, I am unable to explain this wide variability.

In conclusion, my assessment is that this patient has mild and not moderate mitral regurgitation. Although the three beats on the view between an apical 2- and 4- chamber showed moderate MR, this was not representative of the entire study. I do not believe there is a reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a. that the echocardiogram in question demonstrates moderate mitral regurgitation.

Significantly, Dr. Burke also determined that: "[i]n this echocardiogram of November 3, 2001, I found technical limitations

that involved both overtracing of the regurgitant jet area and undertracing the left atrial area."

In response to the Technical Advisor Report, claimant argues that Dr. Burke's finding that moderate mitral regurgitation existed on "the view between an apical 2- and 4-chamber" of her echocardiogram establishes a reasonable medical basis for her attesting physician's finding of moderate mitral regurgitation. Claimant also contends that, by concluding that claimant had only mild mitral regurgitation, Dr. Burke "decided to unilaterally change the terms of the settlement and ignore the moderate [mitral regurgitation] he and Dr. Silvestry observed." Finally, according to claimant, reliance on a single, maximum regurgitant jet to establish the requisite level of mitral regurgitation is acceptable.¹²

After reviewing the entire Show Cause Record before us, we find claimant's arguments are without merit. First, and of crucial importance, claimant does not adequately rebut or address the deficiencies noted by both the auditing cardiologist and the Technical Advisor. Claimant does not rebut the auditing cardiologist's conclusion that claimant had "[m]ild mitral

12. Claimant also asserts that: "[a]lthough the Technical Advisor requested an explanation as to the 'change in the level of regurgitation' and such explanation and information was provided by Dr. Silvestry, it was not addressed by the Technical Advisor in his Report and was obviously summarily disregarded." We disagree. As reflected in the Technical Advisor Report, Dr. Burke specifically reviewed the e-mail from Dr. Silvestry and found that he could not explain the wide variability found on claimant's echocardiogram, even taking into account Dr. Silvestry's explanation.

regurgitation with overestimated RJA + underestimated LAA determined through foreshortening." Nor does claimant challenge the Technical Advisor's finding that Ms. Sage's echocardiogram had "technical limitations that involved both overtracing of the regurgitant jet area and undertracing the left atrial area." There simply is no "reasonable medical basis" for any conclusion of a cardiologist that is based on improper tracings, or any other conduct, that results in an inflated level of regurgitation. As we previously have found, conduct "beyond the bounds of medical reason" can include overtracing the amount of a claimant's regurgitation and characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation. See PTO No. 2640 at 11-12, 15, 22 (Nov. 14, 2002).

We also disagree with claimant's assertion that her claim is payable as the Trust did not meet "its burden to deny payment of this claim." To the contrary, the Audit Policies and Procedures state, in pertinent part, that:

For audits based, in whole or in part, on the grounds that no reasonable medical basis exists for specific answer(s) to the Audit Question(s), the Claimant shall have the burden of proving that there was a reasonable medical basis to support the material representation(s) made by the Attesting Physician in answering the Audit Question(s).

Audit Policies and Procedures § VI.D. As claimant failed to adequately address the auditing cardiologist's and Technical Advisor's findings that she had only mild mitral regurgitation,

she has not met her burden in establishing a reasonable medical basis for her claim.

In addition, we reject claimant's assertion that she may recover Matrix Benefits by the use of a single maximum measurement of the level of mitral regurgitation. In support, claimant proffered a letter from Dr. Silvestry, who concluded, based on a single measurement of "the maximum regurgitant jet," that claimant had moderate mitral regurgitation. We previously have held that for a reasonable medical basis to exist, a claimant must establish that the findings of the requisite level of mitral regurgitation are representative of the level of regurgitation throughout the echocardiogram.¹³ See PTO No. 6997 at 10-11 (Feb. 26, 2007). To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement.

Moreover, we previously have stated that "'[o]nly after reviewing multiple loops and still frames can a cardiologist reach a medically reasonable assessment as to whether the twenty percent threshold for moderate mitral regurgitation has been achieved.'" PTO No. 6897 at 7 (Jan. 26, 2007) (quoting PTO No.

13. Under the Settlement Agreement, moderate or greater mitral regurgitation is defined as a "regurgitant jet area in any apical view equal to or greater than twenty percent (20%) of the left atrial area (RJA/LAA)." Settlement Agreement § I.22. Nothing in the Settlement Agreement suggests that it is permissible for a claimant to rely on isolated instances of what appears to be the requisite level of regurgitation to meet this definition.

2640 at 9). As claimant has not established that the "maximum regurgitant jet" offered in support of her claim is representative of her level of mitral regurgitation, claimant has failed to establish a reasonable medical basis for her claim. This is especially true where, as here, the Technical Advisor concluded that, while certain beats on claimant's echocardiogram demonstrated moderate mitral regurgitation, they were not representative of her level of regurgitation throughout the echocardiogram,¹⁴ which the Technical Advisor found to be only mild. Rather than rebutting these specific determinations made by the Technical Advisor, claimant relies solely on an erroneous interpretation of the Settlement Agreement.¹⁵ On this basis as well, claimant has failed to meet her burden in establishing a reasonable medical basis for her claim.

Finally, we disagree with claimant's arguments concerning the required method for evaluating the level of valvular regurgitation. Moderate mitral regurgitation is defined as an RJA/LAA ratio in the range of 20% to 40%, which is based on the grading system required by the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Although the Settlement Agreement specifies the percentage of regurgitation needed to

14. As also noted by the Technical Advisor, these limited beats were not determined in a standard view of the echocardiogram, but rather "between a 2- and 4- chamber view" of the echocardiogram.

15. For this reason as well, we reject claimant's argument that the Technical Advisor applied an improper standard in determining that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation.

qualify as having moderate mitral regurgitation, it does not specify that actual measurements must be made on an echocardiogram to determine the amount of a claimant's regurgitation. As we explained in PTO No. 2640, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." PTO No. 2640 at 15.

For the foregoing reasons, we conclude that claimant has not met her burden in proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Sage's claim for Matrix Benefits.